UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE ORGANOGENESIS SECURITIES LITIGATION	)	No. 04-10027-JLT

MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANT HERBERT M. STEIN'S MOTION TO DISMISS
THE CORRECTED CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

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INTRODUCTION

Pursuant to Fed. R. Civ. P 12(b)(6) and 9(b), Defendant Herbert M. Stein hereby submits this Memorandum of Law in Support of his Motion to Dismiss the Corrected Consolidated Amended Class Action Complaint ("Complaint") as to the allegations against him, with prejudice.

Defendant Herbert M. Stein was only affiliated with Organogenesis for the first few months of the alleged 27 month class period. Furthermore, the only two statements allegedly attributable to Mr. Stein were made on the very first day of the class period.

Plaintiffs have alleged a class period beginning on November 15, 1999 and ending on February 7, 2002. (Compl. ¶1). They also allege that Mr. Stein only served as an officer of Organogenesis until January 1, 2000, (Compl. ¶31), which is only the first month and a half of the 27 month class period. Plaintiffs also allege that he only served as a director until March 13, 2000, (Compl. ¶81), which is only the first four months of the 27 month class period. Despite recognizing that Stein left Organogenesis almost two full years before the end of the class period, and two and a half years before Organogenesis filed for bankruptcy on September 25, 2002, (Compl. ¶161), plaintiffs have stretched their already thin allegations against others in an effort to tack on claims against Mr. Stein.

The only statements attributed to Mr. Stein that plaintiffs attack were both allegedly made on November 15, 1999 - the very first day of the class period. (Compl. ¶¶68, 70). Plaintiffs should not be allowed to sweep Mr. Stein into this action by relying on general allegations as to "material adverse factors," (Compl. ¶¶59-67), that developed or arose "throughout" or "during" the class period. Plaintiffs fail to sufficiently plead that (a) these adverse factors were in existence at the time Mr. Stein allegedly made his statements on the first day of the class period, (b) the failure to disclose any alleged adverse factors made the statements misleading, or (c) Mr. Stein knew or was reckless in not knowing the existence of these adverse factors when he allegedly made his statements.

Indeed, many, if not all, of the "material adverse factors" were fully disclosed by Organogenesis prior to, at the inception of, and during the class period. In brief, Organogenesis fully disclosed, prior to the dates of the two statements allegedly made by Mr. Stein, the fact that in making the difficult transition from a primarily research based company to a research and manufacturing company, it faced several significant obstacles to ultimate profitability.[1/] Organogenesis disclosed that (a) it did not receive enough revenue from the sale of its product to cover its production and manufacturing costs,[2/] (b) it was uncertain whether it would ever be able to commercially mass-produce Apligraf in sufficient volumes to lower its costs,[3/] (c) that it was dependent on Novartis' ability to market and sell Apligraf,[4/] (d) it had not achieved profitability and warned that it expected to continue to incur net losses, and that it was highly uncertain about the extent of its future losses or when it would achieve profitability,[5/] and (f) that it only had sufficient capital to fund operations in the short-term.[6/]

[1/] See e.g., Organogenesis Form 10-K, March 30, 1999, at 10 (describing the need to "further transition from small-scale to full-scale production of our products") (Stein Appendix, Tab C); Organogenesis Form S-3, May 17, 1999, at 6 (same) (Stein Appendix, Tab D); Organogenesis Form S-3, December 27, 1999, at 8 (same). (Stein Appendix, Tab H).

[2/] E.g., Organogenesis Form 10-Q, August 16, 1999, at 4, 9, 11 (Stein Appendix, Tab E); Organogenesis Form 10-Q, November 15, 1999, at 4, 9, 11. (Stein Appendix, Tab G).

[3/] E.g., Organogenesis Form 10-Q, November 16, 1998, at 10 ("[t]here can be no assurance that the Company will realize sufficient production volume or otherwise reduce its production costs to significantly improve gross margins") (Stein Appendix, Tab B); Organogenesis Form 10-K, March 31, 1999, at 10 ("with increasing demand for Apligraf, we must further transition from small-scale to full-scale production of our products. If we do not make the full transition successfully, we will not be able to satisfy the demands for our products and our results of operations will be hurt") (Stein Appendix, Tab C); Organogenesis Form 10-Q, November 15, 1999, at 15 (disclosing risk of "manufacture and sale of products in sufficient volume to realize a satisfactory margin") (Stein Appendix, Tab G); Organogenesis Form S-3, May 17, 1999, at 4 (disclosing possibilities that it "will be difficult to develop [our products] into commercially-viable products; [it] will be difficult to manufacture [our products] on a large scale") (Stein Appendix, Tab D); Organogenesis Form S-3, December 27, 1999, at 6 (same). (Stein Appendix, Tab H)

[4/] E.g., Organogenesis Form 10-Q, November 15, 1999, at 15 (disclosing risk of "successful marketing and selling of Apligraf by Novartis") (Stein Appendix, Tab G); Organogenesis Form S-3, May 17, 1999, at 5 ("[i]f Novartis does not succeed in marketing and selling Apligraf or gaining international approvals for the product or if we are unable to meet the production demand of global commercialization, our operating results will suffer") (Stein Appendix, Tab D); Organogenesis Form S-3, December 27, 1999, at 7 (same). (Stein Appendix, Tab H)

[5/] Organogenesis Form S-3, May 17, 1999, at 4 ("[w]e have not achieved profitability and expect to continue to incur net losses. The extent of future losses and the time required to achieve profitability is highly uncertain") (Stein Appendix, Tab D); Organogenesis Form S-3, December 27, 1999, at 6 (same). (Stein Appendix, Tab H)

[6/] Organogenesis Form S-3, May 17, 1999, at 7 ("[b]ased upon current plans, we believe existing working capital and future funds from Novartis, including product and royalty revenue, will be sufficient to finance operations into 2000") (Stein Appendix, Tab D); Organogenesis Form S-3, December 27, 1999, at 10 (same). (Stein Appendix, Tab H)

Despite these disclosures, plaintiffs voluntarily chose to take a high-risk, high-reward gamble on a company with what plaintiffs concede was a promising product that was experiencing rapidly increasing sales,[7/] but which had never turned a profit. After these very risks that were fully disclosed materialized, forcing Organogenesis into bankruptcy, the plaintiffs filed this suit in an impermissible attempt to use the securities laws as insurance on their investment. See Fitzer v. Sec. Dynamics Tech. Corp., 119 F. Supp. 2d 12, 23 (D. Mass. 2000) (stating that the fact a company may have run "into management and technology difficulties that ultimately prevented it from succeeding during the Class Period represents an unfortunate loss of opportunity, but that is precisely the risk that every investor takes when investing in a high-technology company whose new products may not succeed"); see also In re Boston Tech., Inc. Sec. Litig., 8 F. Supp. 2d 43, 60 n.20 (D. Mass. 1998) ("[s]urely the reasonable investor recognizes that having all of one's eggs in a single basket, particularly in a high stakes business environment, is risky").

Congress passed the Private Securities Litigation Reform Act of 1995 ("PSLRA") to curb suits routinely brought by plaintiffs seeking to recover a lost investment "whenever there is a significant change in the issuer's stock price, without regard to any underlying culpability of the issuer, and with only faint hope that the discovery process might lead eventually to some plausible cause of action." H.R. Conf. Rep. No. 104-369, at 32 (1995).

ARGUMENT

In order to state a claim under Sections 10(b) or 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b), 78t(a), or Rule 10b-5, 17 C.F.R. § 240.10b-5, plaintiffs must plead that (1) in connection with the purchase or sale of a security, (2) the defendant made a false statement or omitted a material fact, (3) with the requisite scienter, and (4) that plaintiffs' reliance on that statement or omission, (5) caused the injury. E.g., In re Polaroid Corp. Sec. Litig., 134 F. Supp. 2d 176, 181-82

[7/] Sales of Apligraf increased by 400% from the beginning of the class period to its end. This data, compiled from the Complaint and Organogenesis' public filings, was calculated by Defendants Laughlin, Sabolinski, Tuck, Erani, Lopolito, Arcari, and Ades in their Memorandum in Support of Their Motion to Dismiss The Corrected Consolidated Amended Class Action Complaint. ("Co-Defendants' Memorandum").

(D. Mass. 2002) (quoting Gross v. Summa Four, Inc., 93 F.3d 987, 992 (1st Cir. 1996)). The scant allegations related to Mr. Stein in the Complaint patently fail to satisfy these elements.

I. The Complaint As To Mr. Stein Must Be Dismissed Because Plaintiffs Have Failed To Allege Any Actionable False Statements Or Omissions Of Material Fact With The Required Specificity.

The PSLRA reinforced this Circuit's previously well-established strict pleading requirement for fraud. E.g., Carney v. Cambridge Tech. Partners, Inc., 135 F. Supp. 2d 235, 241 (D. Mass. 2001) (quoting Greebel v. FTP Software, Inc., 194 F.3d 185, 193 (1st Cir. 1999)). Even prior to the PSLRA, "[t]his Circuit ha[d] been notably strict and rigorous in applying the Rule 9(b) standard in securities fraud actions." E.g., Guerra v. Teradyne, Inc., No. Civ. A. 01-11789, 2004 WL 1467065 *5 (D. Mass. Jan. 16, 2004) (quoting Greebel v. FTP Software, Inc., 194 F.3d 185, 193 (1st Cir. 1999)); Suna v. Bailey Corp., 107 F.3d 64, 73 (1st Cir. 1997) ("we have repeatedly emphasized Rule 9(b)'s heightened pleading requirements because of our concern that plaintiffs will bring baseless strike suits against securities defendants in order to increase settlement amounts or to engage in a fishing expedition for evidence on which to base their claims").

To meet this heightened pleading requirement, plaintiffs "must not only allege the time, place, and content of the alleged misrepresentations with specificity, but also the factual allegations that would support a reasonable inference that adverse circumstances existed at the time" of the alleged statement. Fitzer, 119 F. Supp. 2d at 18 (quoting Greebel, 194 F.3d at 193-94). Plaintiffs must allege "specific facts supporting the claim that the statements at issue were false or misleading," Boston Tech., 8 F. Supp. 2d at 57. "[E]ach of a plaintiff's allegations must have a sufficiently particular factual predicate." Orton v. Parametric Tech. Corp., 344 F. Supp. 2d 290, 304 (D. Mass. 2004).

"[A] duty to disclose arises only where both the statement made is material, and the omitted fact is material to the statement in that it alters the meaning of the statement." E.g., Carney, 135 F. Supp. 2d at 242 (internal quotations omitted). "A statement is not rendered misleading by omission

merely because the undisclosed fact bears some relation to the subject matter of the statement." Boston Tech., 8 F. Supp. 2d at 53. The duty to disclose "does not mean that by revealing one fact about a product, one must reveal all others that, too, would be interesting, market-wise, but means only such others, if any, that are needed so that what was revealed would not be so incomplete as to mislead." Carney, 135 F. Supp. 2d at 242 (internal citations and quotations omitted). An alleged omission is not actionable therefore, even if it is related to or provides an additional "interesting" context for the affirmative statement.

Finally, to be actionable an alleged statement or omission must be material, meaning that it "would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." Baron v. Smith, 285 F. Supp. 2d 96, 102 (D. Mass. 2003) (emphasis added).

In this Circuit, "securities fraud cases are 'decided by a statement-by-statement analysis in which the inquiry made is restricted to the immediate context of each statement - namely, the balance of what was said on the particular occasion, and the immediate circumstances in which the particular statement was made.'" Carney, 135 F. Supp. 2d at 243 (quoting Boston Tech., 8 F. Supp. 2d at 55).

A. The Plaintiffs Fail To Allege With The Required Specificity That Mr. Stein's Alleged Statements Were Actionable Or Misleading.

Once the convoluted allegations in the Complaint have been sorted out,[8/] it becomes clear that the statements potentially attributable to Mr. Stein are either (a) not alleged to be false or

[8/] This Complaint first groups various alleged "material adverse factors" into a seven page laundry list. (Compl. ¶¶59-67). The allegations in this laundry list are primarily general, conclusory, and extremely repetitive, although they contain enough slight variation to create added confusion as to what plaintiffs are actually attempting to allege. The Complaint then lumps together several statements made over the course of three months and on a wide variety of subjects, many of which are attributable to different individuals, (Compl. ¶¶68-75), and follows that block of statements with a conclusory allegation that those statements were false because they omitted the laundry list of material adverse factors. (Compl. ¶76(a)). This format has allowed plaintiffs to obfuscate, rather than specify (as they are required to do), (a) the exact time that these material adverse factors arose, (b) why or how a duty arose to disclose these factors, and (c) which alleged statement was rendered misleading by any alleged omission. Even before passage of the PSLRA, this Circuit expressed displeasure about having to put such a puzzle together, and to reconstruct or guess why a particular statement is alleged to be false or misleading. See Capri Optics Profit Sharing v. Digital Equip. Corp., 950

materially misleading due to an omitted fact, (b) general, optimistic, immaterial, and non-actionable statements, or (c) were accompanied by full disclosures of known risks and were non-actionable, immaterial forward-looking statements.

First, as discussed above, for a statement to be actionable, a plaintiff must allege specific facts showing why that particular statement was false or misleading at the time it was made, or that it was so incomplete as to mislead due to the omission of a material fact.

Secondly, it is well established that general, vague, or loosely optimistic statements about a company's "current state of affairs or future prospects" are not actionable as a matter of law. In re Peritus Software Serv., Inc. Sec. Litig., 52 F. Supp. 2d 211, 220 (D. Mass 1999) (quoting Boston Tech., 8 F. Supp. 2d at 54). These types of statements are not actionable because it is assumed that "it would be patently unreasonable for an investor to consider 'puffery' when engaged in investment decision making." Boston Tech., 8 F. Supp. 2d at 54 (internal citations omitted). For this reason, "courts have demonstrated a willingness to find immaterial as a matter of law a certain kind of rosy affirmation commonly heard from corporate managers and numbingly familiar to the marketplace…" Parametric, 344 F. Supp. 2d at 300 (quoting Shaw v. Digital Equip. Corp., 82 F.3d 1194, 1217 (1st Cir. 1999)).

It is also well-established in this Circuit that predictions or forward-looking statements are not actionable because such statements are "unlikely, as a matter of law, to be material to a reasonable investor." Carney, 135 F. Supp. 2d at 245. In fact, the PSLRA provides a statutory safe harbor for forward-looking statements.[9/]

F.2d 5, 8 (1st Cir 1991). Other circuits have also expressed displeasure with such complaints. See e.g., In re Syntex Corp. Sec. Litig., 95 F.3d 922, 932-33 n.9 (9th Cir. 1996). It is likely that the plaintiffs have constructed such an obtuse Complaint in order to hide the fact, discussed below, that their claims of fraud against the defendants, and especially Mr. Stein, are inadequate. See Williams v. WMX Tech., Inc., 112 F.3d 175, 178 (5th Cir. 1997) ("A complaint can be long-winded, even prolix, without pleading with particularity. Indeed such a garrulous style is not an uncommon mask for an absence of detail").

[9/] These protected statements include (a) statements projecting revenues or other financial items, 15 U.S.C. § 78u-5(i)(1)(A), (b) statements about plans and objectives of management, 15 U.S.C. § 78u-5(i)(1)(B), and (c) statements about future economic performance. 15 U.S.C. § 78u-5(i)(1)(D). If an individual makes such a forward looking statement, there can be no liability if either (a) that statement is" identified as a forward-looking statement and is

1. The November 15, 1999 Press Release

Plaintiffs attempt to allege that part of Organogenesis' November 15, 1999 press release was materially false when made. But under the law, described above, none of the three sentences quoting Mr. Stein are actionable. Plaintiffs allege that a November 15, 1999 press release quotes Mr. Stein as saying:

> Apligraf is a revolutionary technology development to provide significant advantages in wound healing. Apligraf is FDA approved, **well-received by physicians** and can be a highly cost-effective therapy for many patients. The key remaining piece of the puzzle is gaining broad, standardized reimbursement. **Achieving standardized reimbursement for Apligraf is a top priority at both Novartis and Organogenesis and is being addressed aggressively by both Companies.** (Compl ¶68) (emphasis added by Complaint).[10/]

a. "Well-Received By Physicians"

What plaintiffs appear to take issue with is the statement that Apligraf is "well-received by physicians." In their attempt to show that this statement was false, plaintiffs allege that an "employee" of Novartis stated that physicians "grew frustrated and disappointed with the product because contamination of the product frequently resulted in physicians not receiving the product when necessary." (Compl. ¶62(c)). Plaintiff also allege that a "contractor" for Novartis stated that "physicians grew reluctant to re-order Apligraf because 'they couldn't rely on it - they couldn't rely on it coming through.'" (Compl. ¶62(d)).

First, these alleged statements by these two informants alone do not demonstrate that the product was not, as a matter of fact, well received by physicians at the time of Mr. Stein's alleged

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accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement," 15 U.S.C. § 78u-5(c)(1)(A)(i), or (b) the plaintiff fails to allege that the individual knew the statement was false or misleading. 15 U.S.C. § 78u-5(c)(1)(B)(i). The Complaint attempts to avoid application of this doctrine with the broad blanket allegation that none of the alleged misstatements are protected by the PSLRA safe harbor, (Compl. ¶192), but such generalizations are inapplicable to the statements allegedly made by Mr. Stein for the reasons discussed below.

[10/] The press release also included a disclaimer that stated: "Statements in this press release which are not historical fact, such as discussions of gaining standardized reimbursement, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and involve risks and uncertainties. The Company's actual results may differ significantly from the results discussed in the press release or in other forward looking statements made by management. There can be no guarantee as to the rate of development of Apligraf sales or of successful development of other programs in the pipeline." Organogenesis, Press Release, November 15, 1999, at 2. (Stein Appendix, Tab F).

statement. One informant was an alleged "employee" at Novartis, not Organogenesis, and the other was an alleged "contractor" hired and overseen by Novartis, both of whom were allegedly employed or retained sometime "during" the class period. (Compl. ¶ 62(c) & (d)). One flaw with relying on these two informants to challenge the veracity of Mr. Stein's statement was that plaintiffs have not alleged that these informants were employed at the beginning of the class period when this statement was made. The fact that they were allegedly employed "during the class period" could mean that they were merely employed during some period after Stein allegedly made this statement. See Carney, 135 F. Supp. 2d at 244 (finding no liability for statements where plaintiffs failed to allege that adverse factors that allegedly developed "through the Class Period" were in existence at the time of a statement made on the first day of the class period); Peritus, 344 F. Supp. 2d at 307-08 (finding a general allegation of an adverse factor that occurred "during" the class period was not sufficient enough with respect to time); Teradyne, 2004 WL 1467065 at *16 ("[t]he plaintiffs have failed to specify the status of the company's affairs when the statements were made, and failed to allege how these [adverse] facts - which occurred during the Class Period and beyond - rendered [the] statements made early on, at the beginning of the Period, false"); see also In re Syncor Int'l Corp. Sec. Litig., 327 F. Supp. 2d 1149, 1158-59 (C.D. Cal. 2004) (holding that the failure to allege "job description, job title, dates of employment, and job responsibilities" rendered the allegations based on an informant insufficient) (emphasis added).[11/]

Furthermore, Apligraf sales increased 400% from the first day of the class period to the last. See Co-Defendants' Memorandum. This fact completely contradicts and undermines plaintiffs' allegation that the product was not well-received. Furthermore, Mr. Stein's statement that Apligraf was well-received is the type of optimistic, generalization about the market demand for a product that is non-actionable as a matter of law. E.g., Fitzer, 119 F. Supp. 2d at 26 (holding that the

[11/] As argued below, it is also significant that plaintiffs never allege that Mr. Stein or anyone else at Organogenesis were ever aware of these observations made by the alleged "Novartis employee" and the alleged "Novartis contractor" regarding distribution of Apligraf.

statement that there was "continued market demand" for a product to be non-actionable); Peritus, 52 F. Supp. 2d at 220 (finding the statement "unprecedented market demand" to be non-actionable).

Finally, this statement related to the market acceptance of Apligraf must be examined in its "full context," see id. at 219 (internal citations omitted), which includes the clear disclaimer contained within the press release that "there can be no guarantee as to the rate of development of Apligraf sales." Organogenesis, Press Release, November 15, 1999, at 2. (Stein Appendix, Tab F). Furthermore, in other relevant filings at or around this time, Organogenesis revealed:

- It faced the risk that Apligraf will "fail to obtain acceptance by the medical community." Organogenesis Form S-3, May 17, 1999, at 4 (Stein Appendix, Tab D); Organogenesis Form S-3, December 27, 1999, at 6. (Stein Appendix, Tab H)

- It faced the risk of market acceptance of its products, and successful marketing and selling of Apligraf by Novartis; Organogenesis Form 10-Q, November 15, 1999, at 15. (Stein Appendix, Tab G)

- "Our business results would be hurt if [we] were unable to demonstrate to the medical community the efficacy, relative safety and cost effectiveness of treating patients with our products, or if our products were not accepted as alternatives to other existing or new therapies." Organogenesis Form S-3, May 17, 1999, at 4 (Stein Appendix, Tab D); Organogenesis Form S-3, December 27, 1999, at 6. (Stein Appendix, Tab H)

- "[O]ur collaborators may not be successful in gaining market acceptance for our products." Organogenesis Form S-3, May 17, 1999, at 5 (Stein Appendix, Tab D); Organogenesis Form S-3, December 27, 1999, at 7. (Stein Appendix, Tab H)

These disclaimers, made prior to, at the inception of, and during the class period, are still an additional reason why the statement is non-actionable. See Glassman v. Computervision Corp., 90 F.3d 617, 635 (1st Cir. 1996) (holding that optimistic statements about the prospects of a product made in a company's prospectus were non-actionable because the company had also warned that its product "might never be accepted by the market"). "Moreover, the fact that a new product might face problems in the market is obvious to a reasonable investor, and therefore omission of it is not culpable." Boston Tech., 8 F. Supp. 2d at 63 (internal citations omitted).

b. "The Key Remaining Piece Of The Puzzle Is Gaining Broad, Standardized Reimbursement. Achieving Standardized Reimbursement For Apligraf Is A Top Priority At Both

Novartis And Organogenesis And Is Being Addressed Aggressively By Both Companies."

The November 15, 1999 press release also includes an alleged statement by Mr. Stein that "the key remaining piece of the puzzle is gaining broad, standardized reimbursement. Achieving standardized reimbursement for Apligraf is a top priority at both Novartis and Organogenesis and is being addressed aggressively by both Companies." (Stein Appendix, Tab F). Plaintiffs do not allege that achieving standardized reimbursement was not a top priority or being pursued aggressively. All plaintiffs allege in response to this statement is that "continuing difficulties in obtaining standardized reimbursement were not being adequately addressed by either Organogenesis or Novartis." Compl. (¶76(c)). This type of non-specific, broad, conclusory statement is insufficient to allege that Mr. Stein's statement was false. It does not include any details of when these difficulties were being encountered, how they were being addressed, what these difficulties were, or who at Organogenesis, if anyone, actually knew that these difficulties were not being addressed. Peritus, 52 F. Supp. 2d at 226 (finding allegations were not plead with required specificity because they failed to state the "who, what, when, where and how").

Furthermore, Mr. Stein's alleged statement that achieving standardized reimbursement was a "top priority" and being pursued "aggressively" is the type of vaguely optimistic statement that, as a matter of law, a reasonable investor would not rely upon. Plaintiffs also conveniently ignore the fact that the November 15, 1999 press release specifically included the disclaimer: "[s]tatements in this press release which are not historical fact, such as a discussion of gaining standardized reimbursement, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and involve risks and uncertainties." (Stein Appendix, Tab E) (emphasis added). As discussed above, such forward-looking statements are non-actionable.

Prior to and after this time, moreover, Organogenesis stated "our ability to commercialize our product candidates will depend, in part, upon the availability of reimbursement from third-party

payors…" Organogenesis Form S-3, May 17, 1999, at 7 (Stein Appendix, Tab D); Organogenesis Form S-3, December 27, 1999, at 9. (Stein Appendix, Tab H)

These disclosures of risk also make Stein's alleged statement non-actionable because it was sufficiently qualified so that reliance on it would not be reasonable, as a matter of law.

2. The Form 10-Q For The Third Quarter Of 1999

The only other statement that could allegedly be attributed to Mr. Stein comes from the following excerpt that plaintiffs extracted from the 10-Q for the third quarter of 1999:

> We expect Apligraf commercial sales to increase… [P]roduction costs exceeded product sales due to the start-up costs associated with low volume production. **We expect production volume to increase and our margins to improve.** We expect to continue to **expand manufacturing operations** and advance the product pipeline during the remainder of 1999 and into 2000. (Compl. ¶70) (emphasis added by Complaint).

a. "Production Costs Exceeded Product Sales Due To The Start-Up Costs Associated With Low Volume Production"

Plaintiffs attempt to argue that it was not true that "production costs exceeded product sales due to the start-up costs associated with low volume production" because they allege management knew the agreement with Novartis resulted in Organogenesis losing money on each sale of Apligraf, and that Organogenesis was not reimbursed for any unit of Apligraf manufactured but not sold. (Compl. ¶65).

The deficiencies with plaintiffs' allegations as to the supposed falsity of this statement are numerous. First and foremost is that Organogenesis fully disclosed it was losing money on sales of Apligraf.[12/] The fact that the agreement with Novartis was also disclosed[13/] further undermines plaintiffs' claims of fraud. See In re Galileo Corp. S'holders Litig., 127 F. Supp. 2d 251, 267 (D. Mass. 2001) (holding that plaintiffs could not premise fraud claims based on an accurate disclosure

[12/] Every Form 10-Q and Form 10-K published prior to and during the class period clearly shows that total production costs were well-above total product sales, or sales revenue. For example, see Organogenesis Form 10-Q, August 16, 1999, at 4, 9, 11 (Stein Appendix, Tab E); Organogenesis Form 10-Q, November 15, 1999, at 4, 9, 11. (Stein Appendix, Tab G).

[13/] The agreement was an exhibit to the Organogenesis, Form 10-K, filed on March 29, 1996. (Stein Appendix, Tab A).

of the relevant terms of a supply and distribution agreement); In re Segue Software, Inc. Sec. Litig., 106 F. Supp. 2d 161, 168 (D. Mass. 2000) (dismissing fraud claims based on allegations that press release did not fully disclose terms of contract because the terms at issue were sufficiently disclosed in the 10-K). It is curious why plaintiffs believe these disclosed facts and this disclosed agreement can form the basis of any type of fraud allegation. It is almost as if plaintiffs failed to read the various 10-Qs, 10-Ks, and S-3s filed before, at the inception of, and during the class period, including the 10-Q at issue, that not only showed that the revenue Organogenesis received from product sales was much lower than its production and manufacturing costs, but also that (a) it was uncertain whether it would ever be able to commercially mass-produce Apligraf in sufficient volumes to lower it costs,[14/] (b) that it was dependent on Novartis' ability to market and sell Apligraf,[15/] (c) that it had not achieved profitability and warned that it expected to continue to incur net losses,[16/] (d) that it was highly uncertain about the extent of its future losses, or when it would achieve profitability,[17/] and (e) that it only had sufficient capital to fund operations in the short-

[14/] E.g., Organogenesis Form 10-Q, November 16, 1998, at 10 ("[t]here can be no assurance that the Company will realize sufficient production volume or otherwise reduce its production costs to significantly improve gross margins") (Stein Appendix, Tab B); Organogenesis Form 10-K, March 31, 1999, at 10 ("with increasing demand for Apligraf, we must further transition from small-scale to full-scale production of our products. If we do not make the full transition successfully, we will not be able to satisfy the demands for our products and our results of operations will be hurt") (Stein Appendix, Tab C); Organogenesis Form 10-Q, November 15, 1999, at 15 (disclosing risk of "manufacture and sale of products in sufficient volume to realize a satisfactory margin") (Stein Appendix, Tab G); Organogenesis Form S-3, May 17, 1999, at 4 (disclosing possibility that it "will be difficult to develop [our products] into commercially-viable products, [it] will be difficult to manufacture [our products] on a large scale") (Stein Appendix, Tab D); Organogenesis Form S-3, December 27, 1999, at 6 (same). (Stein Appendix, Tab H).

[15/] E.g., Organogenesis Form 10-Q, November 15, 1999, at 15 (disclosing risk of "successful marketing and selling of Apligraf by Novartis") (Stein Appendix, Tab G); Organogenesis Form S-3, May 17, 1999, at 5 ("[i]f Novartis does not succeed in marketing and selling Apligraf or gaining international approvals for the product or if we are unable to meet the production demand of global commercialization, our operating results will suffer") (Stein Appendix, Tab D); Organogenesis Form S-3, December 27, 1999, at 7 (same). (Stein Appendix, Tab H).

[16/] Organogenesis Form S-3, May 17, 1999, at 4 ("[w]e have not achieved profitability and expect to continue to incur net losses. The extent of future losses and the time required to achieve profitability is highly uncertain") (Stein Appendix, Tab D); Organogenesis Form S-3, December 27, 1999 (same). (Stein Appendix, Tab H).

[17/] Organogenesis Form S-3, May 17, 1999, at 4 ("[w]e have not achieved profitability and expect to continue to incur net losses. The extent of future losses and the time required to achieve profitability is highly uncertain") (Stein Appendix, Tab D); Organogenesis Form S-3, December 27, 1999, at 6 ("[w]e have not achieved profitability and expect to continue to incur net losses. The extent of future losses and the time required to achieve profitability is highly uncertain"). (Stein Appendix, Tab H).

term.[18/] In short, all plaintiffs allege as a basis for fraud are facts clearly disclosed in the filings themselves. Restating such obvious and disclosed facts cannot form the basis of fraud.

Second, the allegation that Organogenesis was not receiving enough revenue from Apligraf sales to cover its manufacturing and production costs, and that the more units it sold the greater its total losses would be, has no bearing on whether Organogenesis would have been capable of lowering its production costs through higher-volume production. The flaw in plaintiffs logic is that they assume, without alleging any facts to show, that production costs would be the same at higher-volume production.

In short, plaintiffs assume in a conclusory manner, without explaining in the required detail, that Organogenesis could not have lowered their production costs through higher-volume production. Plaintiffs neither point to nor reference any marginal cost data, internal reports on production costs, nor any specific terms of the Novartis agreement that would have made it impossible to lower production costs below product sales through higher volume production. See (Compl. ¶¶59-67). When a plaintiff makes an allegation that a company would have been unable to make a profit under the terms of a certain contract, it must specifically describe the provisions of the contract and describe why they prevent the company from ever making a profit, and how these provisions were concealed from investors. Plaintiffs have failed to do this.[19/]

b. "We Expect Apligraf Commercial Sales To Increase…We Expect Production Volume To Increase And Our Margins To Improve. We Expect To Continue To Expand Manufacturing Operations

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[18/] Organogenesis Form S-3, May 17, 1999, at 7 ("[b]ased upon current plans, we believe existing working capital and future funds from Novartis, including product and royalty revenue, will be sufficient to finance operations into 2000") (Stein Appendix, Tab D); Organogenesis Form S-3, December 27, 1999 at 10 (same). (Stein Appendix, Tab H)

[19/] Plaintiffs are attempting to draw the impermissible inference that at the time Mr. Stein made this statement, on the very first day of the class period, it was impossible for Organogenesis to ever make a profit under the Novartis agreement, based solely on the allegations that over the course of the next two years Organogenesis was not able to make a profit. These types of allegations represent impermissible "fraud by hindsight." Fitzer, 119 F. Supp. 2d at 20 (holding that a plaintiff cannot speculate using hindsight that just because a company experienced "a sales slowdown and reduced revenue by the end of the Class Period that statements of good corporate health made at the beginning of the Class Period must have been inaccurate."); Boston Tech., 8 F. Supp. 2d at 53 ("[t]here is no liability where a plaintiff's claim rests on the assumption that defendants must have known of the severity of their problems earlier because conditions became so bad later on") (internal quotations and citations omitted).

And Advance The Product Pipeline During The Remainder Of 1999 And Into 2000."

Plaintiff's allege that the statements in the 10-Q that "[w]e expect Apligraf commercial sales to increase…We expect production volume to increase and our margins to improve. We expect to continue to expand manufacturing operations and advance the product pipeline during the remainder of 1999 and into 2000" were untrue because Novartis was experiencing marketing problems that would prevent it from increasing sales, and that Organogenesis would not increase production volume because of various distribution problems, and because it was losing money on each sale of Apligraf. (Compl. ¶¶62, 65). First, it is exactly these types of statements expressing optimism for future growth in sales and production that represent generally optimistic projections of future results that are not actionable as a matter of law because a reasonable investor would not rely on such typical and commonplace puffery. Parametric, 344 F. Supp. 2d at 302 ("expressing general optimism in [a company's] position for long-term growth is merely corporate puffery"); Boston Tech., 8 F. Supp. 2d at 54 ("vague predictions about the prospects for a new product, or for a company in general, are examples of such non-actionable statements") (internal citations omitted).

Additionally, the repeated use of "expect" indicates that these statements are clearly forward-looking and therefore non-actionable. In fact, the 10-Q expressly provides that "[t]his Form 10-Q contains forward-looking statements that involve risks and uncertainties." Organogenesis, Form 10-Q, November 15, 1999, at 10. (Stein Appendix, Tab E). The 10-Q then specifically provides meaningful cautionary statements identifying important factors that could cause its actual results regarding sales, production volume, margins, and manufacturing expansion to differ from the stated expectation. These disclosed risks included:

- Market acceptance for its products;
- Manufacture and sale of products in sufficient volume to realize a satisfactory margin;
- Successful marketing and selling of Apligraf by Novartis; and

- Manufacturing disruptions or production failures.

Id. at 15. Not only does this specific cautionary language make the statements setting forth Organogenesis' "expectations" not actionable under the PSLRA, but these disclosures of various risks associated with Organogenesis' sales, production volume, margins, and manufacturing expansion undercuts any argument by the plaintiffs that the 10-Q was misleading because it failed to disclose the alleged "material adverse factors."

3. The December 23, 1999 Form S-3 (and its two amendments).

Plaintiffs do not allege that any statements in this Form or the two amendments were false. Additionally, there are no statements in these forms that have any relation to the material adverse factors plaintiffs claim should have been disclosed, hence there was no duty to disclose them even if they were material (which plaintiffs have not shown), even if they existed at the time of these statements (which plaintiffs have not shown), and even if they had been known to exist at the time (which plaintiffs have not shown).

4. The April 21, 2000 Form S-3

Plaintiffs do not allege that any statements in this Form were false. Furthermore, the Complaint states that Mr. Stein had severed all ties with Organogenesis prior to this point in time. (Compl. ¶81). Additionally, there are no statements in these forms that have any relation to the material adverse factors plaintiffs claim should have been disclosed, hence there was no duty to disclose them, even if they were material (which plaintiffs have not shown), even if they existed at the time of these statements (which plaintiffs have not shown), and even if they had been known to exist at the time (which plaintiffs have not shown).

II. The Complaint Must Be Dismissed As To Mr. Stein Because It Fails To Raise A Strong Inference Of Scienter.

Even if the Complaint had managed to allege an actionable false statement or material omission by Mr. Stein, which it did not, the Complaint must still "with respect to each act or

omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2) (emphasis added). Satisfying this standard requires, at the least, alleging facts that demonstrate the "who, what, when, where and how" of the alleged fraud. Peritus, 52 F. Supp. 2d at 226. Factors establishing scienter can include "the particular times, dates, places, or other details of the alleged fraudulent activity. Although these particular factors are not required, per se, their absence from the complaint may be indicative of the excessive generality of the allegations supporting scienter." Parametric, 344 F. Supp. 2d at 306 (internal quotations and citations omitted). Plaintiffs must "point to facts that would support the inference that the defendants knew of and deliberately or recklessly disregarded adverse circumstances that existed at the time the statements were made." Carney, 135 F. Supp. 2d at 244 (internal citation omitted).

"Inferences of scienter survive a motion to dismiss only if they are both reasonable and strong inferences." Id. at 242 (quoting Greebel, 194 F.3d at 195-96) (emphasis added). Merely pleading motive and opportunity is insufficient to raise this inference. Id. (citing Greebel, 194 F.3d at 197).

Not only have plaintiffs failed to allege facts "indicating that undisclosed, adverse circumstances, belying" Mr. Stein's alleged statements existed at the time of those statements, id. at 244, but they have also failed to make the required showing that Mr. Stein "knew of and deliberately or recklessly disregarded such circumstances when he made the statements." Id. Further, any inference of scienter is strongly, if not completely, undercut by a failure to allege any suspicious trades of stock by Mr. Stein.

A. The Complaint Fails To Allege Specific Facts Showing Any Statement Was Known To Be False When Made, Or That Any Material Information Was Omitted With Knowledge.

In general, plaintiffs in securities fraud cases seeking to establish scienter "typically identify internal reports, memoranda, or the like, and allege both the content of those documents and

defendants' possession of them at the relevant time." Boston Tech., 8 F. Supp. 2d at 57. The Complaint in this case, like the one dismissed in Boston Tech., includes no reference to any internal reports, memoranda, or other such documents possessed or read by Mr. Stein.

Instead, plaintiffs in this case attempt to create the required strong inference of scienter through the broad and conclusory opinions held by some unnamed informants. When relying upon informants, a plaintiff must describe that informant with "sufficient particularity to support the probability that a person in the positions occupied by the source would possess the information alleged." Fitzer, 119 F. Supp. 2d at 22 (quoting Novak v. Kasaks, 216 F.3d 300, 313 (2d Cir. 2000)). In addition, as the court in Syncor held, in cases such as this where the timing of the informant's knowledge of the adverse factor is an issue, the dates of employment should be specific.

The Complaint fails to make any sufficient showing that Mr. Stein knew his alleged false statements were false at the time he made them on the first day of the class period. For example:

- As for the allegations by the Novartis "employee" and Novartis "contractor" that, in their opinion, physicians were becoming frustrated with the availability of Apligraf, there are absolutely no allegations that Mr. Stein was aware of this alleged fact at any time, let alone on the first day of the class period when he allegedly made the challenged statement.

  In fact, plaintiffs fail to allege that anyone at Organogenesis was aware of the issues raised by the Novartis employee or the Novartis contractor, and the plaintiffs do not allege that the Novartis employee and the Novartis contractor communicated these opinions to anyone at Organogenesis. See Fitzer, 119 F. Supp. 2d at 25 ("[t]his Court cannot speculate that because former employees in a corporation knew of changes in the sales profiles, the corporate executives must also have known about the changes and fraudulently concealed them…").

- As to the statement about production costs, the individuals allegedly employed at Organogenesis "throughout the class period" and who allegedly had knowledge of the relevant material adverse facts, are quoted in the Complaint as having made vague accusations, not specific to when, who, or how, that "upper management" or the "whole company" was aware of certain material adverse factors. These broad, conclusory, and unsupported allegations from an informant as to when people knew (i.e., "throughout the class period"), how they knew, and who knew (i.e., "upper management" or "the whole company") are insufficient to create a strong inference of scienter.

- Plaintiffs have also failed to allege, with the requisite specificity, that Mr. Stein knew his alleged statements as to commercial sales and production volume in the 10-Q were false when he made them. First, plaintiffs cannot even allege that the statements that "[w]e expect Apligraf commercial sales to increase" and "[w]e expect production volume to increase" were false because those statements turned out to be accurate projections: Apligraf's sales did increase throughout the class period by approximately 400%, Co-Defendants' Memorandum, and Organogenesis did increase its production volume during the class period to approximately 40,000 units per year. (Compl. ¶136). Accurate projections of future results are obviously not actionable false statements. Carney, 135 F. Supp. 2d at 244-45.

Plainitffs' failures to allege scienter are especially fatal to their claims against Mr. Stein given the fact that Mr. Stein was only with Organogenesis for the very beginning of the class period, and the statements he allegedly made occurred on the very first day of the class period. Based on the pleadings alone, therefore, it is impossible to tell whether (a) the alleged material adverse factors even existed during Mr. Stein's brief tenure with Organogenesis, or (b) anyone at Organogenesis was aware of these alleged factors while Mr. Stein was at Organogenesis. Therefore, even if plaintiffs' general accusations of knowledge were sufficient against the other defendants, they are not sufficient to sweep Mr. Stein into this litigation because of the likely possibility that Mr. Stein was no longer with Organogenesis when those factors allegedly materialized, or when knowledge of those factors was allegedly acquired.

B. Plaintiffs' Allegations Regarding Mr. Stein's Registration Of Stock, And His Subsequent Sale Of Stock, That Occurred While He Was No Longer At Organogenesis And Which Caused Him To Lose $7 Million, Creates No Inference Of Scienter At All, Let Alone A Strong Inference.

Plaintiffs allege that on April 21, 2000, which was after he had left the company, Mr. Stein registered to sell approximately 35% of his stock, which plaintiffs misleadingly characterize as "almost half." (Compl. ¶88). Such a registration alone does not raise any inference of scienter. See Bay v. Palmisano, Nos. Civ. A. 01-0949, 01-1509, 01-1510, 01-1801, 2002 WL 31415713 *10 n.16 (E.D. La. Oct. 24, 2002) (holding that mere registrations to sell stock "do not support a strong inference of scienter"). Plaintiffs further allege that Mr. Stein sold a certain amount of this stock, over a year after he left Organogenesis, for a $7 million loss. (Compl. ¶188). These allegations that

Mr. Stein sold less than 35% of his stock at a substantial loss while no longer affiliated with Organogenesis do not create any inference of scienter. Greebel, 194 F.3d at 206 (holding that sales by a former officer during the class period amounting to $19 million out of the $20 million of his total stock sold during the period was not suspicious, as a matter of law); Teradyne, 2004 WL 1467065 at *28 ("the substantial losses by individual defendants 'undermines any inference of scienter'") (quoting Maldonado v. Dominguez, 137 F.3d 1, 12 n.9 (1st Cir. 1998)); see also Crowell v. Ionics, No. CIV. A. 03-10393, 2004 WL 2475332 *15 (D. Mass. Nov. 3, 2004) (finding that "[t]he absence of insider trading does weaken a case for scienter," and that the loss in value of a defendant's stock holdings during the class period "would make the case for scienter even more difficult").

Finally, even if Mr. Stein had sold this stock while he was an insider, and even managed to make a profit, such a sale, as a matter of law, is not sufficiently unusual or suspicious to raise a strong inference of scienter. Greebel, 194 F.3d at 206 (holding "[i]t is not unusual for individuals leaving a company, like [defendant], to sell shares"); Peritus, 52 F. Supp. 2d at 225 (finding that the fact that an insider retained 62% of his stock "suggests that [his] sales were not unusual or motivated by a desire to capitalize on knowledge of inflated stock values"); see also In re Vantive Corp. Sec. Litig., 283 F.3d 1079, 1092 (9th Cir. 2002) (noting unusually long class period of fifteen months, and observing that "it is obvious why [plaintiffs chose such a long class period]; it is not because the allegations found elsewhere in the complaint support an inference of fraud throughout the class period, but because lengthening the class period has allowed the plaintiffs to sweep as many stock sales into their totals as possible, thereby making the stock sales appear more suspicious than they would be with a shorter class period").

III. Plaintiffs Have Failed To Allege Control Person Liability As to Mr. Stein

For the same reasons described in Co-Defendants' Memorandum, plaintiffs have failed to plead a Section 20(a), 15 U.S.C. § 78t(a), claim against Mr. Stein because they "have failed to

allege an underlying violation" of Section 10(b), which is a prerequisite to any Section 20(a) claim, see Suna v. Bailey Corp., 107 F. 3d 64, 72 (1st Cir. 1997), and because they do not allege that any defendant "actually exercised control over" any other defendant. See Aldridge v. A.T. Cross Corp., 284 F.3d 72, 85 (1st Cir. 2002).

CONCLUSION

For the reasons stated above, Mr. Stein respectfully requests this Court dismiss, with prejudice, all the claims against him in the Corrected Consolidated Amended Class Action Complaint.

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By his attorneys,

/s/ Breton Leone-Quick

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